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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/21/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/614,221

Applicant(s)

KARUNANANDAA ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-5, 21, and 25-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 21, 25-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Rejection of Claim 27 under 35 U.S.C. 112 2nd paragraph is withdrawn in view of Applicant's amendments of 3 February 2003.

Rejection of Claims 25-27 under 35 U.S.C. 102(b) are withdrawn in view of Applicant's amendments of 3 February 2003.

Claims 36-39 are objected to under 37 CFR 1.821(d) for their omission of a sequence identifier.

Claim Rejections - 35 USC § 101

Claim 21 remains and newly added Claims 33-39 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicant asserts that to infer protein function from sequence homology is routine and assert that because it is routinely performed that errors do not occur in the assignment of function to an untested protein or DNA sequence (response page 6, lines 22-31) and that the Examiner has not provided any specific factual reasons (i.e. evidence) that undermine the credibility of the asserted utility (response pages 7-8). Applicant cites Venter C. *et al.*, Science, 2001; Vol. 291, pp. 1304-1351; as research indicative of routine structure function prediction. However, Venter *et al.*, state on page 1334 last column to page 1335 column 3, that prediction of gene function with respect to assignment of function using predictive algorithms produces results replete with false positives. The problem of assigning function from structure is further exacerbated by the fact that the prior art does not support a correlation between the structure of the nucleic acids of the claims and the claimed function of the invention. Furthermore, Applicant has not performed

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the most routine of scientific procedures known in the art, namely functional complementation of a mutant in yeast or some other organism to show utility of the claimed invention.

Claims 1, 3-5, 21, 25-27 remain and newly added Claims 28 and 30-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant asserts that the genus of recombinant constructs of the claimed invention have been identified as having an eleven amino acid oxysterol binding protein consensus sequence as a common structural feature, that this defines the claimed invention from other proteins, and that the specification provides guidance for isolating nucleic acids encoding members of the family of oxysterol-binding proteins, and how to assay for elevated phytosterol levels in transformed plants (response page 9 line 16 to page 10 line 11). The prior art does support a correlation between the common structural feature of the invention and the claimed function of the claims. Further, Applicant admits that further experimentation would be required to adequately define the missing link between the structural element of the claimed nucleic acids and the claimed function (i.e. how to assay for elevated phytosterol levels in transformed plants on page 10 line

1 of response)

Claims 1-5, 21, and 25-27 remain and newly added Claims 28-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention.

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Applicant asserts that they have provided protocols for identifying HES1 candidate nucleic acid sequences, protocols for plant transformation, and speculative uses of the claimed invention (response page 11, lines 1-8). Applicant further asserts that they have shown that SEQ ID NO: 1 is a homologue of Yeast HES1 (response page 11 lines 20-25), and assert that although the amount of experimentation is "substantial" and perhaps even laborious, it is not undue (response page 12). Applicant has not taught the function of the claimed invention or any phenotype in a plant expressing the claimed nucleic acid sequence. The homology based correlation of structure with function, i.e. the conserved 11 amino acid oxysterol-binding domain, is not supported in the prior art by a reduction to practice for homologues of the claimed sequences. Furthermore, the oxysterol-binding domain is an apparently ubiquitous motif having been identified in many putative oxysterol-binding EST sequences in the data base, as made evident in Table 4, page 142, of the specification where sequence numbers 5 and 24-29 indicate DNA sequences found in the public databases that show only a putative association with oxysterol-binding activity and no known function. In the absence of any well defined phenotype or function associated with an oxysterol-binding protein in yeast or plants the claims are not enabled.

Claims 1-5, 21, and 27 remain and newly added Claims 34, 36, and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At Claims 1-5 and 21, line 1, and in newly added Claims 34, 36, and 38 "substantially purified" is a relative term and therefore is indefinite. Applicant does not indicate what is encompassed by the other nucleic acid molecules representing the substantially purified natural

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mixture other than SEQ ID NO: 1. Applicant is advised to use art accepted terms, i.e. "An isolated nucleic acid molecule".

Applicant's arguments have been considered but are not considered persuasive. Applicant asserts that they have defined "substantially purified" in the specification and that the term "substantially purified" must also satisfy the phrases drawn to the sequences comprising SEQ ID NO: 1, SEQ ID NO: 622, or a plant HES1 protein (response pages 13-14). The definition of "substantially purified" in the specification recites the term "preferably" several times, lending considerable confusion to the metes and bound of the claim (see the original rejection). Further, the claims read upon a cDNA plant library (i.e. a substantially purified molecule 95% free from other molecules present in the natural mixture). Furthermore, the open language "comprising" in no way links that which is "substantially purified" with "the phrases drawn to sequences comprising SEQ ID NO: 1, SEQ ID NO: 622, or a plant HES1 protein". Thus stated the "substantially purified" molecule could be any nucleic acid or nucleic acids that just happen to "comprise" SEQ ID NO: 1, or a sequence encoding SEQ ID NO: 622 or a plant HES1 protein. In addition the use of the term "comprising" in the above discussed claims should be changed to closed language i.e. --consisting of--.

At Claims 3 and 5, line 1 and in newly added Claims 30 and 32, "specifically hybridizes" is indefinite. The specification on page 17 defines "specifically hybridizes" as two molecules (DNA) capable of forming an anti-parallel, double stranded nucleic acid structure". This would encompass the partial anti-parallel, double stranded nucleic acid fragments that would occur under low stringency hybridization conditions, i.e. 2X SSC at 50° C.

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Applicant asserts that the term "specifically hybridizes" is used only in conjunction with additional clauses drawn to defined nucleic acid sequences (response page 15). The term should also be used in conjunction with highly stringent hybridization conditions. Claims 3 and 5 and newly added Claims 30 and 32 recite either no hybridization conditions or low stringency hybridization conditions and as stated would read upon non-specified nucleic acid sequences and thus are indefinite for failing to set forth the metes and bounds of the claimed nucleic acid sequences. All dependent Claims are included in the rejection

Claim 1-5 and 21 remain and newly added Claims 34, 36, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Ji *et al.* Plant Physiol., 1994 Feb; 104(2):453-459.

Applicant asserts that the language of the claims rejected under 35 U.S.C. 102(b) are not so broad to render these claims anticipated by either "any disclosure of an isolated soybean nucleic acid" or any disclosure of a plant properly selected from the afore mentioned list, which is transformed with an antisense [cDNA] RNA to any protein encoding gene or fragment thereof" (response pages 16-17). The claims do not recite any function for the claimed nucleic acid sequences and since the claims are indefinite as argued supra they are indeed anticipated by the prior art.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

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A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-5, 21, 25-26 remain provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5, 21, 25, and 28 respectively of copending Application No. 10/030,537. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. Please see attached sequence search showing instant SEQ ID NO: 622 = copending SEQ ID NO: 30.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 27 remains and newly added Claims 28-39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 26 of copending Application No. 10/030,537. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to utilize the range of transformed plant species to obtain the instantly claimed range. Furthermore, the further purification of the "substantially purified" molecules of the copending application would have been obvious. The newly claimed domains

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or consensus sequences would have been obvious inherent properties of the copending claimed protein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-5, 21, 25-27, 28-39 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (703) 305-5417. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the Group is (703) 308-4242 or (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding, or if the examiner cannot be reached as indicated above, should be directed to the receptionist, whose telephone number is (703) 308-0196.

Russell Kallis Ph.D.
May 13, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180

David 74